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08/432434

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US006001647A

United States Patent [19]

Peck et al.

[11] Patent Number: **6,001,647**[45] Date of Patent: ***Dec. 14, 1999**[54] **IN VITRO GROWTH OF FUNCTIONAL ISLETS OF LANGERHANS AND IN VIVO USES THEREOF**[75] Inventors: **Ammon B. Peck; Janet G. Cornelius**, both of Gainesville, Fla.[73] Assignee: **Ixion Biotechnology, Inc.**, Alachua, Fla.

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: **08/547,746**[22] Filed: **Oct. 25, 1995****Related U.S. Application Data**

[63] Continuation-in-part of application No. 08/432,434, Apr. 28, 1995, abandoned, which is a continuation-in-part of application No. 08/234,071, Apr. 28, 1994, Pat. No. 5,834,308.

[51] Int. Cl.⁶ **C12N 5/00**[52] U.S. Cl. **435/325; 435/383; 435/384; 435/392**[58] Field of Search **435/325, 383, 435/384, 392**[56] **References Cited****U.S. PATENT DOCUMENTS**

4,439,521 3/1984 Archer et al. .
 4,946,438 8/1990 Reemtsma et al. .
 5,646,035 7/1997 Coon et al. .

FOREIGN PATENT DOCUMENTS

0 363 125 2/1989 European Pat. Off. .
 WO 86/01530 3/1986 WIPO .
 WO 93/00441 1/1993 WIPO .
 WO 94/23572 10/1994 WIPO .

OTHER PUBLICATIONS

Yu et al. (1990) *Tianjin Medical Journal* 18(11):643-47.
 Nielsen (1985) *Acta Endocrinologica*, Suppl. 266:7-39.
 Otonkoski et al. (1994) *Diabetes* 43:1164-66.
 Watanabe et al. (1994) *PNAS USA* 91:3589-92.
 Altman et al. (1984) *Trans. Am. Soc. Artif. Intern. Organs* 30:382-386.
 Hellerstrom et al. (1988) in *The Pathology of the Endocrine Pancreas in Diabetes*, P.J. Lefebvre and D.G. Pipeleers, eds., Springer-Verlag, Heidelberg, Germany, pp. 141-170.
 Rosenberg et al. (1992) in *Pancreatic Islet Cell Regeneration and Growth*, A.I. Vinik, ed., Plenum Press, New York, pp. 95-109.
 Beattie et al. (1994) *J. Clin. Endocrin. Metabol.* 78:1232-40.
 Teitelman et al. (1993) *Development* 118:1031-39.
 Menger et al. (1994) *J. Clin. Invest.* 93:2280-85.
 Wegmann et al. (1993) *J. Autoimmunity* 6:517-27.
 Otonkoski et al. (1994) *Diabetes* 43:947-53.
 Gu et al. (1993) *Development* 118:33-46.
 Bonner-Weir et al. (1993) *Diabetes* 42:1715-20.
 Pictet et al. (1972) in *Handbook of Physiology*, R.L. Pictet et al., eds., Williams & Wilkins, Baltimore, MD, pp. 25-66.

Wang et al. (1987) *Diabetes* 36:535-538.
 Kanaka-Gantenbein et al. (1995), *Endocrinology*, 138(7):3154-3162.
 Nielson, *Diabetes* (1994), 43: No. 2, 7-39.
 Peck et al., *European Journal of Immunology* (1973), 3:385-392.
 Peck et al., *Journal of Immunological Methods* (1973), 3:147-164.
 Pontesilli et al., *Clin. exp. Immunol* (1987), 70:84-93.
 Rao et al., *Cell Differentiation and Development* (1990), 29(3):155-163 (1996).
 Reddy et al., *Diabetologia* (1988), 31:322-328.
 Shieh et al., *Autoimmunity* (1993), 15:123-135.
 Signore et al., *Diabetologia* (1989), 32:282-289.
 Takakai, *In Vitro Cellular & Developmental Biology* (1989), 25:No. 9, 763-769.
 Teitelman, *Tumor Biol.* (1993), 14:167-173.
 Vinik, *Pancreatic Islet Cell Regeneration and Growth* (1992), 1-5.
 Wang et al., *Diabetes* (1987), 36:535-538.
 Yu, et al., *Tianjin Medical Journal*, (1990), 18:No. 11, 643-47 (1990).
 Kuo et al., *Pancreas*, (1992), 7(3):320-325.
 Kuo et al., (Abstract), *Clinical Research*, (1990), 28(1):58A.
 Anderson et al., *Autoimmunity* (1993), 15:113-122.
 Baekkeskov et al., *Nature*, (1990), 347:151-156.
 Baekkeskov et al., *Nature* (1982), 298:167-169.
 Bendelac et al., *The Journal of Immunology* (1988), 141:2625-2628.
 Bendelac et al., *J. Exp. Med.* (1987) 166:823-832.
 Brelje et al., *Diabetes* (1994), 43(2):263-273.
 Gazdar et al., *Proc. Natl. Acad. Sci.* (1980), 77:No. 6,3519-3523.
 Hamashima et al., *Cellular, Molecular and Genetic Approaches to Immunodiagnosis and Immunotherapy* (1987), 219-226 (1987).
 Hanafusa et al., *Diabetes*, (1988), 37:204-208.
 Jarpe et al., *Regional Immunology* (1990/1991), 3:305-317.
 Korsgren et al., *Uppsala J. Med. Sci.* (1993), 98:No. 1, 39-50.
 McEvoy et al., *Endocrinology* (1982), 111:No. 5, 1568-1575.
 Miller et al., *The Journal of Immunology* (1988), 140(1):52-58.

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[57] **ABSTRACT**

The subject invention concerns new methods which make it possible, for the first time, to grow functional islets in vitro cultures. The subject invention also concerns the use of the in vitro grown islet-like structures for implantation into a mammal for in vivo therapy of diabetes. The subject invention further concerns a process using the in vitro grown islet implants for growing an organ in vivo that has the same functional, morphological and histological characteristics as those observed in normal pancreatic tissue. The ability to grow these cells in vitro and organs in vivo opens up important new avenues for research and therapy relating to diabetes.

19 Claims, 11 Drawing Sheets